

063148

510(k) SUMMARY

DATE PREPARED

13 October 2006

SUBMITTER

JAN 17 2007

Eileen Vennum, RAC
President
McMerlin Dental Company
1610 W. Polo Road, Suite A
Grand Prairie, TX 75052
Telephone: 972.602.3746

DEVICE NAME

Common name: Hydrogel Oral Wound Dressing
Trade name: "Sock It!" Oral Pain Gel
Classification name: This device is unclassified under 21CFR Parts 862-892.

PREDICATE DEVICES

K933741 Carrasyn Oral Wound Dressing (marketed as "OraPatchTM")
K953423 Carrasyn Oral Wound Dressing (marketed as "OraPatchTM" and OraBanTM)
K964852 RadiaCare Oral Wound Rinse (marketed as "SaliCeptTM Oral Stomatitis Rinse")
K983182 Caraloe Oral Rinse (marketed as "Carrington Oral Wound RinseTM")
K012126 Salicept Oral Patch (marketed as SaliCeptTM Freeze Dried Gel [FDG])

DEVICE DESCRIPTION

"Sock It!" Oral Pain Gel is a clear, viscous hydrogel wound dressing composed entirely of food-grade ingredients including a food-grade preservative system. It is safe if swallowed, is designed to be physiologically compatible with both intact and compromised tissue in the mouth, and will manage the pain associated with all types of injuries to the mouth.

The gel's primary mode of action for pain relief is that it adheres to the wound surface, conforms to the contours of the wound, and protects the wound from contamination and irritation by forming a protective barrier that is similar to the natural mucosa. It also creates and maintains a moist wound environment, which is necessary for the natural healing process. The pH and osmotic pressure of the gel are adjusted to be compatible with saliva.

INTENDED USE

The indications for “Sock It!” Gel are the same as those for the predicate devices. This product manages the pain in all types of oral wounds, mouth sores, injuries and ulcers of the oral mucosa. It adheres to oral tissue and forms a protective barrier between the wound and further irritation and contamination. It provides the moist wound environment required for optimal wound healing. Examples of oral lesions include canker sores (aphthous ulcers), tooth extraction sites, oral mucositis, oral stomatitis, traumatic ulcers such as caused by braces and dentures, and irritation and pain following deep tooth scaling.

This product is appropriate for all patient populations.

TECHNOLOGICAL CHARACTERISTICS

Three of the predicate devices are hydrogel wound dressings that have been freeze-dried to produce a fibrous-like material similar to a roll of cotton. This “bandage” material is placed on an oral wound, where it re-hydrates to a hydrogel through contact with saliva. Two of the predicate devices are hydrogel wound dressings that have been freeze-dried to produce a powder. These are re-hydrated by the consumer who adds water at the time of use. The resulting thin hydrogel is swished around inside the mouth to coat the oral mucosa. All five of these predicate hydrogels provide pain relief by coating damaged mucosa and protecting it from further contamination and irritation. [Note: All five predicate devices are predicated upon Carrington Laboratories’ hydrogel wound dressing (K902345) that, like “Sock It!” Gel, is hydrated at the factory and sold in a tube as a hydrated gel.]

Rather than use saliva to re-hydrate the hydrogel “bandage” in the mouth or rely on the consumer to add the correct amount of water to re-hydrate the powdered hydrogel immediately prior to use, “Sock It!” hydrogel is hydrated during manufacture and sold in a tube in the traditional hydrated gel form.

The non-substantial difference in design between “Sock It!” gel and the five predicate devices is the time and manner in which water is incorporated into the hydrogel—1) in the mouth with saliva, 2) by the consumer in the container immediately prior to use, or 3) at the factory prior to filling the tube. Regardless of which method is used for hydration, all of these hydrogels adhere to the wound surface, conform to the contours of the wound, and manage pain by forming a protective hydrogel barrier over the wound, similar to undamaged natural mucosa. All these hydrogel barriers manage pain by protecting the wound from contamination and irritation. They all slowly dissolve in the mouth, and all are safe if swallowed.

“Sock It!” Oral Pain Gel is substantially equivalent in design to the five predicate devices.

PERFORMANCE STANDARDS

No performance standards are established for this product under Section 514 of the Act.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2007

Ms. Eileen Vennum
President
Merlin Group DBA McMerlin Dental Company
1610 West Polo Road, Suite A
Grand Prairie, Texas 75052

Re: K063148
Trade/Device Name: "Sock It!"™ Oral Pain Gel
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: MGQ
Dated: January 5, 2007
Received: January 8, 2007

Dear Ms. Vennum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

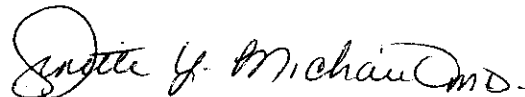
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "J. Y. Michael MD.", is positioned above the printed name and title.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE (PROFESSIONAL)

510(k) Number (if known): K063148

Device Name: "Sock It!"TM Oral Pain Gel (hydrogel oral wound dressing)

This product manages the pain in all types of oral wounds, mouth sores, injuries and ulcers of the oral mucosa. It adheres to oral tissue and forms a protective barrier between the wound and further irritation and contamination. It provides the moist wound environment required for optimal wound healing.

Manages pain of, for example:


- All types of oral wounds, mouth sores, injuries and ulcers of the oral mucosa
- Canker sores and cold sores
- Irritation and traumatic ulcers such as those caused by various appliances such as braces, brackets, full and partial dentures and palatal expanders
- Soft tissue pain from orthodontics
- Aphthous ulcers
- Extraction site pain
- Oral mucositis and stomatitis
- Irritation and pain following tooth scaling and prophylaxis

Prescription Use X AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

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(Sign-Off)
Division of Anesthesiology, General Hospital,
Pain Control, Dental Devices
Number: K063148

INDICATIONS FOR USE (OTC)

510(k) Number (if known): K063148

Device Name: "Sock It!TM" Oral Pain Gel (hydrogel oral wound dressing)

This product manages the pain in all types of oral wounds, mouth sores, injuries and ulcers of the oral mucosa. It adheres to oral tissue and forms a protective barrier between the wound and further irritation and contamination. It provides the moist wound environment required for optimal wound healing.

Manages pain of, for example:

- All types of oral wounds, mouth sores, injuries and ulcers of the mouth
- Canker sores and cold sores
- Irritation and traumatic ulcers such as those caused by various appliances such as braces, brackets, full and partial dentures and palatal expanders
- Aphthous ulcers
- Irritation and discomfort from ill-fitting dentures

Prescription Use _____ AND/OR Over-The-Counter Use X
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

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